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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393	
33771 7590 09/27/2007 PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L.			EXAMINER		
			PELLEGRINO, BRIAN E		
SUITE 115	OIXIE HIGHWAY		ART UNIT	PAPER NUMBER	
MIAMI, FL 33	MIAMI, FL 33180			3738	
			MAIL DATE	DELIVERY MODE	
		•	09/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Disposition of Claims  ### Disposition is Find a Boylected to by the Examiner.  ### Disposition is sobjected to by the Examiner.  #### Disposition is Sobjected to by the Examiner.  ##### Disposition is Sobjected to by the Examiner.  ###################################	•	Application No.	Applicant(s)			
Brian E. Pellegrino 3738  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  **SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  **SHE 71K, 91K, 91K/91K bits from the misling date of this communication.  **If NO period for rugh is specified above, the maintained shabotry period will apply and will expire \$10K, 91K/91K from the misling date of this communication.  **If NO period for rugh is specified above, the maintained shabotry period will apply and will expire \$10K/91K from the mainty date of this communication.  **If NO period for rugh is specified above, the mainting date of the communication will be a specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of the communication and period to the specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of this communication is the specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of this communication.  **If NO period for rugh is specified above, the mainting date of the rught specified above,		10/696,174	JAYARAMAN, SWAMINATHAN			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 3 CFR 1.130(i), in revent, however, may a reply be timeny field  1 ft NO period for reply is assented above. He maintains statution period with apply and will acade Sk (0) MONTH's from the mailing date of this communication.  Failur to reply within his sof or carded period for reply is assented above. He maintains statution period with apply and will acade Sk (0) MONTH's from the mailing date of this communication.  Failur to report with the provision and the provision of the application of the provision of the maintain and period of the application of the applicati	Office Action Summary	Examiner	Art Unit			
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1)⊠ Responsive to communication(s) filed on @9 July 2007. 2a)☐ This action is FINAL. 2b)⊠ This action is non-final. 3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)☑ Claim(s) 54-61,64 and 67-69 is/are pending in the application. 4a) Of the above claim(s) is/are plowed. 6)☑ Claim(s) is/are allowed. 6)☑ Claim(s) is/are objected to. 8)☐ Claim(s) is/are objected to. 8)☐ Claim(s) is/are objected to. 8)☐ Claim(s) is/are objected to by the Examiner. 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)☐ All b)☐ Some * ○]☐ None of. 1.☐ Certified copies of the priority documents have been received. 2.☐ Certified copies of the priority documents have been received in Application No 3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received.	<ul> <li>WHICHEVER IS LONGER, FROM THE MAILING DA</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period w</li> <li>Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing</li> </ul>	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ti vill apply and will expire SIX (6) MONTHS fror , cause the application to become ABANDON	N. mely filed nthe mailing date of this communication. ED (35 U.S.C. § 133).			
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#### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/9/07 has been entered.

## Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54,56-59,64,68 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (WO 91/12779). Figs. 1,17 show a plurality of stent performs 12 to form a stent 10. Fig. 4 shows a stent perform with a metallic core 22 and an outer sheath 14 disposed about the contact surface. It can be seen (Figs. 12,15,17) that end caps exist on the core to encapsulate the ends of the wire. Wolff discloses the sheath on the metallic core can include a therapeutic agent, page 10, lines 35,36. Wolff et al. also disclose that the sheath is a polymer and can be bioabsorbable, page 12, lines 16-18. It is inherent there is pores in the sheath or coating since it allows for elution of the drug,

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page 10, lines 36-38. Additionally, Wolff discloses two therapeutic agents could be used, page 15, lines 19,20.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. WO 91/12779 in view of Liprie et al. (6491662). Wolff et al. is explained supra. Wolff does disclose the stent can be made from self-expanding material, page 10, line 27. However, Wolff fails to explicitly disclose the core stent material is made of shape memory alloy. Liprie et al. teach that a core is made of shape memory alloy to strengthen the vascular device, col. 2, lines 36-43. It would have been obvious to one of ordinary skill in the art to substitute metal materials and use a SMA as taught by Liprie with the stent of Wolff et al. such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp.

Claims 60,61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Barclay et al. (2002/77693). Wolff et al. is explained supra. Wolff et al. does disclose multiple polymer layers can be used, Fig. 3B and page 15, lines 11-21. However, Wolff et al. fail to disclose the drug is coated over the sheath and also using a release layer. Barclay et al. teach (Fig. 5E) a stent 139 can have an outer sheath 141A and then a drug layer 147 and then a release layer 143. This enables the drug to be delivered to the lumen tissue and not the blood. It would

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have been obvious to place the drug layer on a sheath layer and then a release layer of polymer on the stent as taught by Barclay et al. with the stent filaments of Wolff et al. such that it can treat the lumen.

Claims 67,69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Sukhatme (2005/261283). Wolff et al. is explained supra. Wolff does teach combinations of drugs can be used, page 17, line 14. However, Wolff et al. fail to disclose the drug is selected from cyclosporine A, imatinib mesylate, curcumin, and rapamycin. Sukhatme also teaches that rapamycin and imatinib mesylate can be used to effectively treat hyperplasia, paragraphs 117,151,164. It would have been obvious to one of ordinary skill in the art to utilize the teachings of Sukhatme of combining drugs such as rapamycin with the drug imatinib mesylate to be used in the stent of Wolffet al. to treat vascular disease such as restenosis.

# Response to Arguments

Applicant's arguments with respect to claims 54-61,64,67-69 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 7:30am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN E. PELLEGRINO

Brian E Rellegruno

TC 3700, AU 3738